K132542

Premarket Notification
Stryker Neurovascular
TransGate™ Guide Catheter

510(k) Summary

Summary Date: August 9. 2013

Submitter Name and Address:
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA. 94538

NOV 15 2013

Contact:
Anjali Atal-Gupta
Senior Regulatory Affairs Specialist
Phone: 510 413-2573
Fax: 510 413-2588
Email: anjali.atal-gupta@stryker.com

Trade Name: TransGate™ Guide Catheter

Common Name: Guide Catheter

Classification Name: Percutaneous Catheter /Class II device under 21 CFR 870.1250 (Product Code: DQY).

Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K093184 (Nov 6, 2009)	Codman & Shurtleff, Inc. Envoy® Guide Catheter
K010853 (Apr 18, 2001)	Boston Scientific Guider Softip™ XF 5F Guide Catheter
K980453 (Aug 11, 1998)	Boston Scientific Guider Softip™ XF 6F Guide Catheter

Premarket Notification
Stryker Neurovascular
TransGate™ Guide Catheter

Device Description:

Stryker Neurovascular's TransGate Guide Catheters are constructed with polytetrafluoroethylene (PTFE) on the inner lumen for lubricity, stainless steel wire reinforcement within the wall for trackability, torque transmission and strength, and polymer materials along the length of the catheter for support and flexibility. The catheter has an atraumatic tip, a hub for device connectivity and device handling, and a strain relief at the hub for kink resistance. The distal segment of the device shaft is radiopacified and, in addition, a radiopaque marker is embedded at the distal tip of the device to aid visualization under fluoroscopy.

The Stryker Neurovascular TransGate Guide Catheter has straight (ST) and pre-shaped distal tips, available in 40 (40), and Multipurpose (MP) shapes. The TransGate Guide Catheters are offered in both 90 and 100 cm lengths and 5 and 6 French diameters.

Indications for Use / Intended Use:

TransGate™ Guide Catheters are intended to facilitate placement of interventional devices into the coronary, peripheral and neurovasculature.

Accessories:

There are no accessories to the TransGate™ Guide Catheters.

510(k) Summary Of Safety And Effectiveness (cont.)

Comparison to Predicate Device:

	TransGate Guide Catheter (Subject Device)	Codman Envoy Guiding Catheter	Boston Scientific Guider Softip XF 5F and 6F Guide Catheters
510(k) Number	TBD	K093184	K980453, K010853
Classification	Class II, DQY	Class II, DQY	Class II, DQY
Indication	TransGate Guide Catheters are intended to facilitate the placement of interventional devices into the coronary, peripheral, and neurovasculature.	The … is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.	The … is intended to facilitate the placement of interventional devices into the coronary, peripheral, and neurovascular systems.
Materials			
-Shaft Materials	PTFE lined, nylon/thermoplastic elastomer with stainless steel braid	PTFE lined nylon/polyurethane with stainless steel braid[1]	PTFE lined nylon/thermoplastic elastomer/thermoplastic polyester with stainless steel braid
-Proximal End Configuration	Hub with female luer conical lock fitting	Hub with female luer conical lock fitting	Hub with female luer conical lock fitting
-Radiopacity	Radiopaque tip with distal marker	Radiopaque distal tip	Radiopaque distal tip
-Packaging	Catheter attached to SBS packaging card inside Nylon/PE/Tyvek pouch, inside SBS carton	Catheter attached to packaging card inside pouch, inside carton	Catheter attached to SBS packaging card, inside PET/LDPE/Tyvek pouch, inside SBS carton
-Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Dimensions			
Effective Length	5F: 90 cm, 100 cm 6F: 90 cm, 100 cm	5F: 90 cm , 100 cm 6F: 90 cm, 100 cm	5F: 90 cm, 100 cm 6F: 90 cm, 100 cm
Outer	5 F: 1.75 mm	5F: 1.65 mm	5F: 1.70 mm

[1] Materials used for Envoy are not known with certainty

	TransGate Guide Catheter (Subject Device)	Codman Envoy Guiding Catheter	Boston Scientific Guider Softip XF 5F and 6F Guide Catheters
Diameter	6F: 2.1 mm	6F: 2.0 mm	6F: 2.0 mm
Inner Diameter	5F: .057 in 6F: .072 in	5F: .056 in 6F: .070 in	5F: .053 in 6F: .064 in
Tip Shapes	40, MP, Straight	MPD*, MPC*, Straight	40, MP, Straight

*MPD is similar to 40 tip shape and MPC is similar to MP shape

Design verification of the TransGate™ Guide Catheters consisted of:

Performance Test	**Result**
Kink Distance	Met established criteria
Torque Degrees Rotation to Kink	Met established criteria
Tip Shape Retention	Met established criteria
Distal Shaft Flexibility	Met established criteria
Pushability	Met established criteria
Tensile Strength	Met established criteria
Chemical Compatibility	Met established criteria
Corrosion Resistance	Met established criteria
Particulate	Met established criteria
Liquid Leakage	Met established criteria
Air Leakage	Met established criteria
Unscrewing Torque	Met established criteria
Resistance to Overriding	Met established criteria
Stress Cracking	Met established criteria
Ease of Assembly	Met established criteria
Luer Gauging	Met established criteria
Luer Separation Force	Met established criteria
Freedom from leakage and damage under high static pressure	Met established criteria
Flow Rate Testing	Characterization test
Radiopacity	Met established criteria

Testing was conducted in accordance with EN ISO 10555-1, EN ISO 10555-2, and EN 1707.

Shelf Life Testing (Product and Packaging) and Distribution / Shipping Challenge Conditioning and Testing were performed and the devices met established criteria.

Packaging Verification Testing complies with EN ISO 11607-1 and -2 and assessed the ability of finished packages to withstand the effects of anticipated hazards of the distribution environment on essential packaging characteristics and the ability of packaging to protect the device and to maintain sterility (sterile barrier testing).

Biocompability and Sterilization testing were conducted in accordance with EN ISO 10993-1 and EN ISO 11135-1. TransGate Guide Catheters have been classified according to EN ISO 10993-1:2009, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* as follows:

Category: *Externally Communicating*
Contact type: *Circulating blood*
Contact Duration: *Limited exposure (< 24 hours)*

Based on this classification, tests relevant to the device described within this premarket notification were selected and conducted in accordance with EN ISO 10993-1 and its applicable sub-parts.

The TransGate Guide Catheter devices meet ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals limits specified in EN ISO 10993-7:2008, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*. All process and product sterilization validation activities have been conducted and completed in accordance with EN ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*. The sterility of the devices conforms to the requirements of EN 556-1:2001, *Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: requirements for terminally sterilized medical devices*.

A sterility assurance level (SAL) of 10^{-6} has been demonstrated.
Test samples consisted of 2X EtO sterilized devices (entire device).

Testing showed the device, including its packaging, to be biocompatible for its intended use as an externally communicating, circulating blood contacting device as classified under EN ISO 10993-1:2009. The TransGate Guide Catheter successfully passed all of the following biocompatibility tests:

Test	Method
Hemolysis	MEM Elution Assay
Sensitization	Kligman Maximization
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test
Hemocompatibility	Complement Activation
	Hemolysis
	Inactivated Partial Thromboplastin Time Test
	In vitro hemocompatibility
Physicochemical Tests Plastics	USP <661> Aqueous Extraction
Fourier Transform Infrared (FTIR) Scan	FTIR
Latex	ASTM D6499-07
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test
EtO Residuals	Ethylene oxide and Ethylene chlorohydrins residuals

Conclusion:

Because intended use and indications for use are the same as for the predicate devices, and because there is no difference in the fundamental scientific technology of the devices, and because risk assessments and successful verification testing, including testing to EN ISO 10555-1 and EN ISO 10555-2, raise no new questions of safety and effectiveness, Stryker Neurovascular has determined the TransGate™ Guide Catheters to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

Stryker Neurovascular
% Ms. Anjali Atal-Gupta
Senior Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, CA 94538

Re: K132542
Trade/Device Name: TransGate™ Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Atal-Gupta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132542

Device Name: TransGate™ Guide Catheter

Indications For Use:

TransGate™ Guide Catheters are intended to facilitate the placement of interventional devices into the coronary, peripheral, and neuro vasculature.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S